

Article 16. – CANCER DRUG REPOSITORY PROGRAM

68-16-1. **Definitions.** As used in these regulations for the cancer drug repository program, the following terms shall have the meanings specified:

- (a) "Board" means the Kansas State Board of Pharmacy.
- (b) "Cancer drug" or "drug" means a prescription drug that is used to treat any one of the following:
 - (1) Cancer or side effects of cancer.
 - (2) the side effects of any prescription drug that is used to treat cancer or side effects of cancer.
- (c) "Cancer drug repository" means a hospital, nonprofit clinic, physician's office, or pharmacy that has notified the b of its election to participate in the cancer drug repository program.
- (d) "Cancer drug repository donor form" means the cancer drug repository form provided by the board.
- (e) "Cancer drug repository receipt form" means the cancer drug repository receipt form provided by the board.
- (f) "Dispense" has the meaning specified in K.S.A. 65-1626(h).
- (g) "Dispensing Physician" has the meaning specified in K.A.R. 100-21-1.
- (h) "Distribute" has the meaning specified in K.S.A. 65-1626(j).
- (i) "Distributor" has the meaning specified in K.S.A. 65-1626(k).
- (j) "Hospital" has the meaning specified in K.S.A. 65-425.
- (k) "Manufacture" has the meaning specified in K.S.A. 65-1626(q).
- (l) "Nonprofit clinic" has the meaning specified in K.S.A. 65-1664(a)(3).

- (m) "Pharmacist" has the meaning specified in K.S.A. 65-1626(s).
 - (n) "Original Sealed" means originally sealed by the manufacturer or a pharmacy.
 - (o) "Pharmacy" has the meaning specified in K.S.A. 65-1626(u).
 - (p) "Practitioner" means a person licensed to practice medicine or surgery by the Kansas board of healing arts.
 - (q) "Prescription drug" means any drug, including label and container according to context, which is dispensed pursuant to a prescription order.
 - (r) "Side effects of cancer" means symptoms of cancer.
 - (s) "Single-unit-dose packaging" means a single-unit container for articles intended for administration as a single dose, direct from the container.
 - (t) "Tamper-evident unit dose packaging" means a container within which a drug is sealed so that the contents cannot be opened without obvious destruction of the seal.
- (Authorized by and implementing L. 2005, ch.121; effective P-_____.)

68-16-2. Requirements for participation by physicians, pharmacies, hospitals and nonprofit clinics. (a) To be eligible for participation in the cancer drug repository program a physician, pharmacy, hospital, or nonprofit clinic shall comply with all applicable federal and state laws and administrative rules.

(b) Each physician, pharmacy, hospital and nonprofit clinic that elects to participate in the cancer drug repository program shall provide to the board written notification of the following:

(1) The name, street address, and telephone number of the participating physician, pharmacy, hospital or nonprofit clinic.

(2) The name and telephone number of a contact person employed by the physician, pharmacy, hospital or nonprofit clinic.

(3) Whether the physician, pharmacy, hospital or nonprofit clinic will be dispensing donated cancer drugs. (Authorized by and implementing L. 2005, ch.121; effective P-_____.)

68-16-3. Donation of cancer drugs. (a) Donation of a cancer drug shall only be accepted from:

- (1) An individual who is 18 years old or older; or
- (2) a physician, pharmacy, hospital, manufacturer, or distributor.

(b) Only a cancer drug that meets the following criteria shall be accepted:

- (1) The drug has not been compounded.
- (2) The drug has not been previously dispensed from a cancer drug repository;
- (3) The drug's expiration date is at least 6 months later than the date that the drug was donated.

(4) The drug is in its original sealed, unopened, tamper-evident unit dose packaging and the package includes the drug's lot number and expiration date. If repackaged the expiration date shall one year from date of repackaging or the expiration date established prior to donation, whichever is less. Single-unit dose drugs may be accepted if the single-unit-dose packaging is unopened.

- (5) The drug is not adulterated or misbranded.

(c) A cancer drug may be accepted only if the donor simultaneously provides the cancer drug repository a completed cancer drug repository donor form signed by the person making the donation.

(d) A cancer drug repository shall not accept the donation of a controlled substance.

(e) A cancer drug repository shall receive donated drugs only at the premises of a cancer drug repository and only by a person authorized by the repository to receive donated cancer drugs. A drop box may not be used to deliver or accept donations.

(f) *A cancer drug donated under the cancer drug repository program shall be stored in a secure storage area under environmental conditions appropriate for the drugs being stored. Donated drugs shall be stored separately from and not commingled with non-donated drugs. (Authorized by and implementing L. 2005, ch.121; effective P-
_____.)

68-16-4. Dispensing requirements. (a) Prior to dispensing a donated cancer drug, the pharmacist or dispensing physician shall inspect the cancer drug for adulteration, misbranding, and the expiration date. A cancer drug shall not be dispensed if it is adulterated, misbranded, or if its expiration date has passed.

(b) Prior to a donated cancer drug being dispensed, it shall be labeled identifying it as a medication dispensed from a cancer drug repository.

(c) A cancer drug shall be dispensed only to a cancer patient.

(d) At the time the cancer drug is dispensed the recipient shall be orally notified that the drug may have been previously dispensed.

(e) Before a cancer drug may be dispensed to a recipient, the recipient shall sign a cancer drug repository recipient form, which shall include an acknowledgment that the recipient was orally notified that the drug might have been previously dispensed.

(f) A donated cancer drug may be removed from a unit-dose package and dispensed in a vial if the pharmacist or dispensing physician determines that to do so is in the best interest of the patient. Only a pharmacist, pharmacy technician, pharmacy student, or dispensing physician may remove a cancer drug from a unit-dose package and repackage the drug.

(g) A donated cancer drug may be dispensed no more than one time after being donated. (Authorized by and implementing L. 2005, ch.121; effective P-

_____.)

68-16-5. Handling fees. A cancer drug repository may charge the recipient a handling fee of no more than 300% of the Medicaid dispensing fee or \$15.00, whichever is less, for each cancer drug dispensed. (Authorized by and implementing L. 2005, ch.121; effective P-_____.)

68-16-6. Distribution of donated cancer drugs. (a) A cancer drug repository may distribute drugs donated under the cancer drug repository program to another cancer drug repository if requested by that cancer drug repository.

(b) At the time a cancer drug repository distributes a drug to another participating cancer drug repository, the distributing repository shall complete a cancer drug repository donor form. The form completed by the distributing repository and a copy of the cancer drug repository donor form that was completed by the original donor shall be provided to the receiving cancer drug repository at the time of distribution.

(c) The distributing repository shall maintain, for a period of five years, a copy of the forms provided to the receiving drug repository at the time of distribution.

(Authorized by and implementing L. 2005, ch.121; effective P-
_____.)

68-16-7. Sale of donated drug. Donated drugs shall not be sold. Violation of this section may result in the loss of the ability to participate in this program as well as any other penalties that may be imposed pursuant to the Kansas pharmacy act. (Authorized by and implementing L. 2005, ch.121; effective P-_____.)

68-16-8. Recordkeeping requirements. (a) Cancer drug repository donor and recipient forms shall be maintained at least 5 years. The original donor form shall remain with the drug until it is dispensed to a patient.

(b) A repository that destroys donated cancer drugs shall create a written record of the destruction that contains the following information and shall maintain the record for at least 5 years:

- (1) The date the cancer drug was destroyed;
- (2) the name, strength and quantity of the cancer drug destroyed;
- (3) the name of the person or entity that destroyed the cancer drug; and
- (4) The name of the person or entity from which the cancer drugs were received.

(Authorized by and implementing L. 2005, ch.121; effective P-
_____.)